

**SELF CERTIFICATION OF COMPLIANCE WITH FDA REQUIREMENTS
TO BE RETURNED WITH BID**

a. I certify that I am a licensed practitioner and/or other person regularly and lawfully engaged in the manufacture and/or refurbishing of the medical device items identified below. I also certify that prior to sale or use of such devices I will take necessary steps to assure that such devices are not adulterated or misbranded within the meaning of those terms in the Federal Food, Drug and Cosmetic Act (21 U.S.C. 311, et seq.)

Item Number(s) _____

Print Name _____

Title _____

Full Address _____

Telephone Number _____

(Sign) _____ Date _____

or

b. Recognizing that Federal law places stringent restrictions on adulterated or misbranded medical devices (21 U.S.C. 331, et seq.), I certify that I either will sell or otherwise proffer the medical device items identified below only to the persons described in a above; I will not use those items for their original or usual intended use or for any other medical use.

Item Number(s) _____

Print Name _____

Title _____

Full Address _____

Telephone Number _____

(Sign) _____ Date _____

1. False or misleading statements may result in a fine of not more than \$10,000 or imprisonment for not more than 5 years, or both (18 U.S.C. 1001).